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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,367	10/24/2003	Audrey Minden	0575/55311-AZ-PCT-US	2322
7590 10/18/2004			EXAMINER	
John P. White, Esq. 1185 Avenue of the Americas New York, NY 10036			SZPERKA, MICHAEL EDWARD	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/693,367

**Applicant(s)**

MINDEN, AUDREY

**Examiner**

Michael Szperka

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 65-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/24/03</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Applicant's amendment to the first line of the specification, dated March 1, 2004 is acknowledged. Applicant is reminded that the status and relationship of the priority documents to the instant application must be indicated. As such, Applicant should amend the first line of the specification to indicate that U.S.S.N. 09/718,032 has issued as U.S. Patent No. 6,667,168, and that U.S.S.N. 09/082,737 has issued as U.S. Patent No. 6,013,500.

Applicant's amendment to the claims, dated October 24, 2003 is acknowledged.

Claims 1-64 have been canceled.

Claims 65-68 have been added.

Claims 65-68 are pending and under consideration in this application.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicant's IDS, filed October 24, 2003 is acknowledged. The reference to Melnik, GenBank Accession No. AF005046 has been lined through on Applicant's IDS and added to an 892 form to correct errors and clarify the record. It is noted that

sequence AF005046, deposited at NCBI on May 21, 1997, was not available to the public until January 5, 1999 and therefore is not applicable as prior art.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 65-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claim recites an antibody capable of binding to a PAK4 kinase. Antibody binding can be either specific or non-specific in nature, with non-specific binding allowing the antibody in question to bind many additional proteins unrelated to PAK4. It is reasonable to conclude that many of these additional proteins, and the antibodies that bind them, have been previously disclosed in the prior art. Amending the base claim to recite, for example, "An antibody capable of specifically binding ..." would obviate this rejection.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 65-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant has claimed an antibody that is capable of binding a mammalian PAK4 serine/threonine kinase, but the disclosure does not indicate that such an antibody was generated at the time of the invention. The disclosure provided by applicant does contain a partial sequence of mouse PAK4 (SEQ ID NO: 14), the full-length sequence of human PAK4 (SEQ ID NO: 2), a deletion mutant that lacks the GTPase binding domain, and the human point mutants K(350)M, S(474)M and S(474)E. The disclosure also indicates on page 14, lines 20-37, that "polypeptide analogs, fragments or derivatives of antigenic polypeptides which differ from naturally-occurring forms in terms of the identity or location of one or more amino acid residues ... and which share some or all properties of naturally-occurring forms" are contemplated as part of the invention. However, other than for the already indicated deletion and point mutants, the structure and properties of these PAK4 analogs, fragments, and derivatives are not disclosed, nor is it disclosed how the structures of PAK4 analogs, fragments, and derivatives relate to their functional properties. As such, the variation in structure and functional properties of such a genus of molecules is substantial.

Thus, Applicant has claimed the broad genus of antibodies that bind PAK4 derived from any mammal when only the species of a complete human sequence and a partial mouse sequence are disclosed. Additionally, the broadest reasonable interpretation of Applicant's claimed invention reads on antibodies that bind any allelic

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variant, analog, fragment, or derivative of any mammalian PAK4. MPEP section 2163.05 clearly states that when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

As indicated above, there is substantial variation within the genus of mammalian PAK4 full-length sequences, analogs, fragments and variants. This variation necessitates an even greater variation within the genus of antibodies that can bind the genus of mammalian PAK4 full-length sequences, analogs, fragments and variants. Since there is high variability amongst the genus of antibodies of the claimed invention, and Applicant has disclosed only a limited amount of the genus of molecules bound by said antibodies, the claimed invention does not have written support within the originally filed specification. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, which make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 65-68 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. PAK4 serine/threonine kinases are found in nature, and as such an antibody that binds PAK4 could also be found in nature, such as in the serum of a non-immunized animal. Amending the base claim to recite, for example, "An isolated and purified antibody ..." would obviate this rejection.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 65-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Plowman et al., U.S. Patent Application Publication No. US 2003/0050230 (see entire document).

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Plowman et al. disclose two polypeptide sequence identified as PAK5, one partial sequence (SEQ ID NO: 30 of Plowman et al., 398 amino acids long) and one full-length sequence (SEQ ID NO: 103 of Plowman et al., 591 amino acids long), although only the partial sequence is disclosed in the preliminary application dated April 14, 1998 (see additionally pages 27-28, paragraphs 350-368). Both sequences are 100% identical to SEQ ID NO: 2 (571 amino acids long) of the instant application over their entire length. Plowman et al. also claim an antibody or antibody fragment having specific binding affinity to the kinase polypeptide PAK5 or to a kinase domain peptide of PAK5 (see page 9, paragraphs 63-69, and claim 21 from Plowman et al.). These antibodies to PAK5 can be either monoclonal or polyclonal (see page 9, paragraphs 63-69, and claim 21 from Plowman et al.). As all 398 amino acids of PAK5 as disclosed by Plowman et al. are contained in PAK4 (SEQ ID NO: 2) of the instant application, an antibody that specifically binds to the PAK5 of Plowman et al. would necessarily bind to PAK4 of the instant application. Therefore, the prior art anticipates the claimed invention.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 6, 2004



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